PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant/ Appellant:	Cheryl A. Pederson; Jennifer S. Ma; Nancy J. Dyslin	Confirmation No.	4710
Serial No.:	09/729,034	Docket No.:	56094US002 (1004-108US01)
Filed:	December 4, 2000	Customer No.:	32692
Examiner:	Vivek D. Koppikar	Group Art Unit:	3626
Title:	METHODS FOR MANAGING INFECTION RISK INCIDENT TO SURGICAL PROCEDURES IN HEALTH CARE PROVIDER ENVIRONMENTS		

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office on and the date indicated below via the Office electronic filing system.

August 10, 2010	/Judy L. Hansen/
Date	Signature Judy L. Hansen

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief responsive to the Examiner's Answer mailed on June 10, 2010.

Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 13-3723.

TABLE OF CONTENTS

REAL PARTY IN INTEREST

The real party in interest is 3M Innovative Properties Company, of Saint Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 12-49 are now on Appeal in this case.

Claims 12-22 and 26-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al. (Guideline for prevention of surgical site infection) (hereafter "Mangram") in view of Ormond-Walshe, Sarah (Computerized databases in infection control) (hereafter "Ormond-Walshe") and in further view of Blume (US 6,157,853) and in further view of Mushabac (US 5,562,448) and in further view of Sullivan (US 2002/0077865) and in further view of Afsah (US 6,509,730).

Claims 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe, in further view of Blume, in further view of Mushabac, in further view of Sullivan, in further view of Afsah, and in further view of Jacober (US 6,662,081).

Claims 1-11 are currently canceled and are not on appeal.

Claims 12-21 and 37-49 are also rejected under 35 U.S.C. 112, sixth paragraph. The rejections under 35 U.S.C. 112, sixth paragraph are new grounds of rejection advanced in the Examiner's Answer, and allege that Applicant's written description fails to disclose structure, material or acts for the claimed function of the features recited in compliance with 35 U.S.C. 112, sixth paragraph.

STATUS OF AMENDMENTS

The claims were amended on June 3, 2009 in response to the first Examiner's Answer. The claims now on appeal are those submitted in the Amendment filed on June 3, 2009.

SUMMARY OF CLAIMED SUBJECT MATTER

Claims 12, 13, 22 and 37 are independent claims. Independent claims 12, 13 and 37 are at least partially drafted in means-plus-function format in compliance with 35 USC §112, sixth paragraph.

Independent claim 12 recites a computer-implemented system for managing the risk or occurrence of surgical site infection incident to a surgical procedure.[1] The computer-implemented system comprises means for identifying a plurality of stages of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage and a postoperative stage,[2] and means for identifying one or more points-of-care within each identified stage of operative care associated with the surgical procedure.[3] For each point-of-care associated with the surgical procedure, the system includes means for identifying one or a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection,[4] wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility.[5]

The system also includes means for identifying one or more compliance indicators associated with the surgical procedure for the one or plurality of health care delivery practices associated with the surgical procedure within each point-of-care associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators,[6] wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.[7] For each of the compliance indicators, the system includes means for generating a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule[8] to thereby align the health care delivery practices associated with the surgical procedure into rule compliance and to provide a perioperative process map of delivery practices spanning the plurality of stages of operative care

[1] Appellant's specification at page 4, lines 24-27.
[2] Appellant's specification at page 5, lines 5-8.
[3] Appellant's specification at page 5, lines 9.
[4] Appellant's specification at page 6, lines 27-28, and Appellant's specification at page 7, lines 6-9.
[5] Appellant's specification at page 7, line 25 to page 8, line 7.
[6] Appellant's specification at page 10, lines 37-43.
[7] Appellant's specification at page 11, lines 1-2.

associated with the surgical procedure to thereby manage the risk or occurrence of surgical site infection incident to the surgical procedure.[9] The various "means" recited in claim 12 are disclosed as being encoded in hardware or software.[10]

Independent claim 13 recites a system for managing the risk or occurrence of surgical site infection incident to a surgical procedure.[11] The system comprises means for constructing a perioperative process map of practices for the delivery of the surgical procedure.[12] The map comprises a plurality of health care delivery practices associated with the surgical procedure and one or more indicators of compliance with the one or more health care practices,[13] wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility,[14] and wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care practices.[15] The system also includes means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure,[16] wherein the means for monitoring the compliance indicators generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure.[17] The various "means" recited in claim 13 are disclosed as being encoded in hardware or software.[18]

Dependent claim 14 depends from independent claim 13, and further recites means for recording the compliance indicators.[19] Dependent claim 18 also depends from independent claim 13, and further recites means for monitoring one or more indicators of outcome.[20] The

---

[8] Appellant's specification at page 13, lines 23-25.
[9] Appellant's specification at page 3, lines 15-18.
[10] Appellant's specification at page 13, lines 13-14.
[11] Appellant's specification at page 4, lines 24-27.
[12] Appellant's specification at page 4, lines 25-27.
[13] Appellant's specification at page 10, lines 39-43.
[14] Appellant's specification at page 7, line 25 to page 8 line 10.
[15] Appellant's specification at page 10, line 43 to page 11, line 2, and page 12, lines 23-30.
[16] Appellant's specification at page 10, lines 37-39.
[17] Appellant's specification at page 13, lines 19-25.
[18] Appellant's specification at page 13, lines 13-14.
[19] Appellant's specification at page 13, lines 21-22.
[20] Appellant's specification at page 10, lines 37-41.

various "means" recited in various dependent claims are disclosed as being encoded in hardware or software.[21]

Independent claim 22 recites a computer-implemented method for managing risks of surgical site infection incident to a surgical procedure.[22] The method comprises selecting, via a computer, for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection,[23] and evaluating, via the computer, a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure.[24] The method further comprises storing, via the computer, data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure,[25] and identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure,[26] wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.[27]

Independent claim 37 recites a computer-implemented system for managing risks of surgical site infection incident to a surgical procedure.[28] The system comprises means for selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection,[29] and means for evaluating a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure.[30] The system also comprises means for storing data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure,[31] and means for identifying via a compliance indicator when the data indicative of the given practice associated

---

[21] Appellant's specification at page 13, lines 13-14.
[22] Appellant's specification at page 4, lines 24-27.
[23] Appellant's specification at page 7, line 25 to page 8, line 10.
[24] Appellant's specification at page 12, line 23 to line 27.
[25] Appellant's specification at page 7, lines 7-10.
[26] Appellant's specification at page 13, lines 19-25.
[27] Appellant's specification at page 10, line 43 to page 11, line 2, and page 12, lines 23-30.
[28] Appellant's specification at page 4, lines 24-27.
[29] Appellant's specification at page 7, line 25 to page 8, line 10.
[30] Appellant's specification at page 12, line 23 to line 27.
[31] Appellant's specification at page 7, lines 7-10.

with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure,[32] wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.[33] As with claim 12, the various "means" recited in claim 37 are disclosed in Appellant's specification as being encoded in hardware or software.[34]

Dependent claim 38 recites that the means for identifying via the compliance indicator when the data indicative of the given practice is not in compliance with the rule comprises means for generating a flag for the data.[35] Dependent claim 39 further recites means for prompting medical personnel to take further action when the flag is generated.[36] Dependent claim 40 further recites means for clearing the flag when the further action is taken. [37]

Dependent claim 41 recites means for generating a perioperative process map of a plurality of practices in a plurality of stages, the plurality of stages including at least a prepoperative stage, an intraoperative stage, and a postoperative stage.[38] Dependent claim 42 recites for each stage of the perioperative process map: means for evaluating practices that pose infection risks during the given stage of the surgical procedure,[39] means for storing data indicative of each of the practices as executed by one or more persons involved with the surgical procedure;[40] and means for identifying when the data indicative of any of the practices is not in compliance with a rule established for the given practice.[41]

Dependent claim 43 recites that the means for identifying when the data indicative of any of the practices is not in compliance with the rule established for the given practice comprises means for generating a flag for the data indicative of one of the practices not in compliance with the rule established for that practice.[42] Dependent claim 44 recites means for prompting medical

---

[32] Appellant's specification at page 13, lines 19-25.
[33] Appellant's specification at page 10, line 43 to page 11, line 2, and page 12, lines 23-30.
[34] Appellant's specification at page 13, lines 13-14.
[35] Appellant's specification at page 13, lines 23-25.
[36] *Id.*
[37] *Id.*
[38] Appellant's specification at page 5, lines 5-8.
[39] Appellant's specification at page 6, lines 12-18.
[40] Appellant's specification at page 13, lines 21-25.
[41] Appellant's specification at page 12, lines 19-29 and page 13, lines 21-25.
[42] Appellant's specification at page 13, lines 21-25.

personnel to take further action when the flag is generated.[43] Claim 45 recites means for clearing the flag when the further action is taken.[44]

Dependent claim 46 recites means for evaluating each of a plurality of practices associated with the surgical procedure that pose infection risks during the surgical procedure; [45] means for storing data indicative of each of the practices as executed by one or more persons involved with the surgical procedure; [46] and means for identifying when the data indicative of one or more of the practices associated with the surgical procedure is not in compliance with a respective rule established for a respective practice.[47]

Dependent claim 49 further comprises means for generating a report that represents a compilation of measurement data associated with the surgical procedure.[48]

With respect to dependent claims 38-49, the various "means" are disclosed in Appellant's specification as being encoded in hardware or software.[49]

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first ground of rejection to be reviewed on Appeal is the rejection of claims 12-21 and 37-49 under 35 U.S.C. 112, sixth paragraph.

The second ground of rejection to be reviewed on Appeal is the rejection of claims 12-21 and claims 26-49 under 35 U.S.C. 103(a) as being over Mangram in view of Ormond-Walshe, in further view of Blume, in further view of Mushabac, in further view of Sullivan, and in further view of Afsah.

The third ground of rejection to be reviewed on appeal is the rejection of claims 23-25 under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe, in further view of Blume, in further view of Mushabac, in further view of Sullivan, in further view of Afsah, and in further view of Jacober.

---

[43] Appellant's specification at page 13, lines 23-25.
[44] *Id.*
[45] Appellant's specification at page 12, line 23 to line 27.
[46] Appellant's specification at page 7, lines 7-10.
[47] Appellant's specification at page 13, lines 19-25.
[48] Appellant's specification at page 12, lines 27-28.
[49] Appellant's specification at page 13, lines 13-14.

ARGUMENT

Claims 12-21 and 37-49 stand rejected under 35 U.S.C. 112, sixth paragraph, based on an allegation that Appellant's specification fails to recite corresponding structure, material or acts for the claimed function. However, Appellant's specification at page 13, line 13 to page 14, line 2 clearly articulate structure, material or acts, in the form of "software or hardware," "software-encoded devices," and "devices that operate across a computer network or the internet." The rejections under 35 U.S.C. 112, sixth paragraph are discussed in greater detail below under a separate heading.

Claims 12-21 and claims 26-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over a six-way combination of references. Specifically, claims 12-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe and in further view of Blume and in further view of Mushabac and in further view of Sullivan and in further view of Afsah. The rejections of claims 12-21 and 26-49 are discussed in greater detail below under a separate heading, and the rejections of claims 34-36 are also argued under another separate heading.

Claims 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over a seven-way combination of references. Specifically, claims 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe, in further view of Blume, in further view of Mushabac, in further view of Sullivan, in further view of Afsah, and in further view of Jacober. Claims 23-25 are discussed in greater detail below under a separate heading.

Appellant respectfully traverses the current rejections for many different reasons addressed below, and requests reversal by the Board of Patent Appeals. Appellant respectfully requests separate review by the Board for each of the issues argued under separate headings.

The Patent Examiner bears the burden of proof to demonstrate a prima facie case that an invention is not patentable.[50] In reviewing an Examiner's decision on Appeal, the Board must consider all of the evidence, and patentability is determined by a preponderance of the evidence with due consideration to persuasiveness of argument.[51]

[50] *See In re Oetiker,* 977 F.2d 1443.
[51] *Id.*

In order for an invention to be patentable, among other things, the invention must have been non-obvious to a person of ordinary skill in the art at the time of the invention.[52] The Supreme Court recently clarified the standard of non-obviousness under 35 U.S.C. 103(a) in *KSR Int'l Co. v. Teleflex, Inc.*[53] As reiterated by the Supreme Court in *KSR International Co.* v. *Teleflex Inc.* (KSR),[54] the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham* v. *John Deere Co.*[55] Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

(1) Determining the scope and content of the prior art;

(2) Ascertaining the differences between the claimed invention and the prior art; and

(3) Resolving the level of ordinary skill in the pertinent art.

In *KSR*, the Supreme Court explained that the Examiner must identify a logical reason why a person of ordinary skill in the art would have been led to make a modification or combination to arrive at the claimed invention. An invention composed of several elements is not proved obvious merely by demonstrating that each of the elements was independently known.[56]

Consistent with *KSR*, the Federal Circuit has stated that there must be "some rationale, articulation, or reasoned basis" to support the legal conclusion of obviousness."[57] The reason for modification need not conform to the particular motivation or objective of the patent applicant.[58] However, there still must be some need or problem known in the art that would have provided a reason for combining elements in the manner claimed.[59]

Furthermore, a basic premise of the obviousness analysis set forth in *KSR* is that the combination of prior art references must actually disclose the elements recited in the claims. Consistent with this premise, the Manual for Patent Examining Procedure (MPEP) sets forth

---

[52] 35 U.S.C. 103(a).
[53] *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).
[54] *Id.*
[55] 383 U.S. 1, 148 USPQ 459 (1966).
[56] *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).
[57] *Alza Corp. v. Mylan Laboratories*, 80 USPQ2d 1001, 1005 (Fed. Cir. 2006) (citing *In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006)).
[58] *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).
[59] *Id.*

three basic requirements to an obviousness analysis as follows.[60] First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.[61]

The *KSR* case clarified that the "suggestion or motivation" requirement is more broadly a requirement that the Examiner articulate a "rational reason" for the modification. However, the *KSR* case did not modify the basic requirement of the obviousness analysis that requires the Examiner to show that the prior art collectively teaches the elements of Appellant's claims. Accordingly, if Appellant can show that the prior art lacks a teaching of one or more elements of the pending claims, the obviousness rejections must be reversed. In addition, if there no *rational* reason a person of ordinary skill in the art would have arrived at the claimed invention in view of the prior art, the obviousness rejections must be reversed.

FIRST GROUND OF REJECTION UNDER APPEAL

Claims 12-21 and 37-49 stand rejected under 35 U.S.C. 112, sixth paragraph, based on an allegation that Appellant's specification fails to recite corresponding structure, material or acts for the claimed function. However, Appellant's specification at page 13, line 13 to page 14, line 2 clearly articulate structure, material or acts, in the form of "software or hardware," "software-encoded devices," and "devices that operate across a computer network or the internet."

Claims 12-21 and 37-49 are drafted in compliance with 35 U.S.C. § 112, sixth paragraph. With respect to the means plus function claims, 35 U.S.C. § 112, sixth paragraph, specifically authorizes means plus function terminology and mandates that such a claim: "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." In this case, Appellant's specification provides clear support for structure, material or acts, in the form of "software or hardware," "software-encoded devices," and

[60] See MPEP 2143.
[61] See MPEP 2143.

"devices that operate across a computer network or the internet."[62] On this basis, the rejections under 35 U.S.C. 112, sixth paragraph are improper and must be withdrawn.[63]

SECOND GROUND OF REJECTION UNDER APPEAL

(Claims 12-22 and 26-49)

For purposes of this Appeal, Appellant will focus primarily on the features recited in claim 22, which was not rejected under the first grounds for rejection. Appellant's independent claim 22 recites a computer-implemented method for managing risks of surgical site infection incident to a surgical procedure. The method comprises selecting, via a computer, for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, and evaluating, via the computer, a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure. The method further comprises storing, via the computer, data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure, and identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure, wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.

Appellant's independent claim 37 recites features that are similar to those of claim 22, but recites such features in means plus function format, in the context of a system. Appellant's independent claims 12 and 13 also recite features that are similar in many respects to those of claim 22, but claims 12 and 13 are more specific in requiring a perioperative process map. For purposes of this appeal, as mentioned above, Appellant will primarily focus the following discussion on claim 22. Similar arguments also apply to independent claims 37, 12 and 13.

In the current rejections of claims 12-22 and 26-49, the Examiner cited Mangram as teaching "evaluating a practice associated with a surgical procedure that poses an infection risk," as required by claim 22. The Examiner recognized that Mangram fails to disclose "storing data indicative of the practice associated with the surgical procedure," as required by claim 22, but

[62] Appellant's specification at page 13, line 13 to page 14, line 2

cited Ormond-Walshe as teaching this feature. The Examiner concluded that it would have been obvious to modify the techniques of Mangram concerning prevention of infection risks with computerized databases in the medical field, as taught by Ormond-Walshe in order to arrive at a technique that evaluates a practice associated with a surgical procedure that poses an infection risk, and stores data indicative of the practice associated with the surgical procedure.

Next, the Examiner recognized that the combination of Mangram and Ormond-Walshe still fails to disclose or suggest identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice, as required by claim 22. However, the Examiner stated that this feature is well known in the art as evidenced by Blume and Mushabac.

Specifically, the Examiner recognized that the combination of Mangram and Ormond-Walshe fails to disclose or suggest identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice (independent claims 22 and 37). Similarly, the Examiner also recognized that the combination of Mangram and Ormond-Walshe fails to disclose or suggest generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule (independent claims 12 and 13). However, the Examiner stated that these features are well known in the art, as evidenced by "the combined teachings of Blume and Mushabac."

In contrast to the Examiner's allegations, however, nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or techniques that generate a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Blume and/or Mushabac with the teaching of Mangram or Ormond-Walshe.

The entire passage of Blume relied upon by the Examiner is reproduced below:

> Data received from localizers 20, and the processing by processor 32 to present a graphical representation on display 40 of the magnetic field produced by magnet 14 must be fast enough to provide "real-time" feedback for a surgeon; i.e., the feedback must be rapid enough to allow decisions to be made during a surgical procedure involving the movement of the implanted magnetic device 30. The method of Procrustes is used to compute the 4.times.4 rigid body transformation between coordinates in the imaging system and coordinates in the localizer system. Thereafter, the 4.times.4 matrix may be applied to transform a pre-stored representation of a magnetic field into a magnetic field having the position and orientation sensed by localizers 20 using standard programming techniques on a presently-available Intel PENTIUM.RTM.-based processor (such as a typical PC), or a Silicon Graphics workstation, with the transformation being accomplished in sufficient time to provide a display that is updated rapidly enough for surgical purposes. Column 7, lines 16-33.

Contrary to the Examiner's conclusion, this teaching in Blume has no relevance with respect to the features recited in Appellant's claims, which concern computer-implemented systems for managing the risk or occurrence of surgical site infection. In contrast to Appellant's claims, the above passage of Blume describes the use of magnets in a surgical procedure to provide the surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device. Thus, this teaching of Blume has no relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection, and lacks any teaching pertinent to such endeavors.

Furthermore, the teaching of Blume cited above clearly lacks any suggestion of identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or generating a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). Accordingly, the Examiner's contentions with respect to Blume are factually incorrect.

Similarly, the teaching of Mushabac relied upon by the Examiner is also irrelevant to the features of Appellant's claims. The relied upon passage of Mushabac is reproduced below.

> Advantageously, the computer provides the dental practitioner operating the dental tool with an alert signal regarding deviation between an actual position and

> orientation of the tool during the use of the tool on the patient and the optimal position and the optimal orientation, as determined prior to the dental operation. The alert signal may take the form of an auditory signal, for example, a verbal message or instruction synthesized by the computer. Alternatively or additionally, the alert signal may include a visual indication provided on the monitor. An alert signal may also be provided in a practice operation, to indicate to the operator a deviation or a conformity of the practice instrument to the predetermined, recommended position and orientation thereof. Column 4, lines 56 to column 5, line 2.

This passage of Mushabac also lacks any relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection. Instead, this passage of Mushabac describes a dental tool that generates an audible or visible alert when the dental tool is mis-positioned.

An alert that is generated when a dental tool is mis-positioned is nothing akin to the features of Appellant's claims, e.g., identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). A person of ordinary skill in the art would not have had any rational reason to modify any computer-implemented system for managing the risk or occurrence of surgical site infection (e.g., per a combination of Mangram and Ormond-Walshe) to generate a flag when a surgical procedure is not in compliance with a rule, or to identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure.

Indeed, the teachings of Blume and Mushabac are completely unrelated to those of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac and Blume. To be sure, Blume describes a system that provides a surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device, and Mushabac describes a dental tool that generates an alert when the tool is mis-positioned.

These teachings concern totally different endeavors than those of Mangram and Ormond-Walshe and include no teachings pertinent to the management of infection in surgical procedures.

Furthermore, even if the alert generation in Mushabac could be reasonably construed as generating a flag, the alert in Mushabac occurs when a dental tool becomes misaligned, and has no relevance to compliance of a surgical procedure with a rule, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure.

In short, neither Mushabac nor Blume discloses or suggests computerized identification of data associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or computerized generation of a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13).

To the extent that Mushabac teaches the generation of an alert, the alert of Mushabac relates to dental tool misalignment, and has no relevance to the management of risks of surgical site infection incident to the surgical procedure. Furthermore, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac and Blume. Indeed, positioning of implanted magnetic devices, per Blume, and dental tools that generate alerts when the tools are mis-positioned, per Mushabac, are not reasonably pertinent to the teachings of Mangram concerning prevention of surgical site infection, nor reasonably pertinent to the teaching of Ormond-Walshe concerning computerized databases for infection control. For each of these reasons, the current rejections must be reversed.

Notwithstanding theses deficiencies in the Examiner's position regarding Mangram and Ormond-Walshe in view of Mushabac and/or Blume, Appellant previously filed an RCE at the Examiner's request (see the Examiner's suggestion in the Office Action mailed June 5, 2007) and attempted to modify the claims specifically to address the Examiner's concerns at that time. However, in response to these attempts to advance the Application, the Examiner applied additional references (namely the Sullivan and Afsah references), which appear to have little or no relevance to the systems and features that Appellant is attempting to patent. Furthermore, the relied upon portions of Sullivan and Afsah are not even prior art to Appellant's claims.

Specifically, the Examiner recognized that a combination of Mangram, Ormond-Walshe, Blume and Mushabac fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as specifically required by claims 12 and 13. Claims 22 and 37 similarly require *selecting for a given health care facility* a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection.[64] For this feature, the Examiner cited Sullivan (specifically section **[0055]**) and argued that it would have been obvious to further modify the combination of Mangram, Ormond-Walshe, Blume and Mushabac in view of this passage of Sullivan.

Appellant traverses this portion of the Examiner's argument for two reasons. First, the cited passage of Sullivan does not qualify as prior art to Appellant's claims. Second, the cited passage of Sullivan appears to be wholly irrelevant to the feature "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility."

Section **[0055]** of Sullivan is reproduced below:

> [**0055**] **FIG. 23** is another illustration of a screen display of a prescription medicine template.

The Examiner's assertion of Sullivan is inappropriate. This cited section of Sullivan in no way suggests any feature even remotely akin to "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claims 12 and 13 or "*selecting for a given health care facility* a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection" as required by claims 22 and 37. On the contrary, FIG. 23 of Sullivan shows nothing more than a screen shot of a prescription medicine template that has no relevance to a surgical procedure. Moreover, nothing in FIG. 23 appears to be selectable for a given health care facility, in any way.

In addition, section **[0055]** of Sullivan is not even prior art to Appellant's claims. The application for the Sullivan patent was filed on November 2, 2001, which is after Appellant's

[64] It should be noted that in the analysis of claim 22, the Examiner failed to even address the step of claim 22 that recites *selecting for a given health care facility* a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection.

filing date of December 4, 2000. While Sullivan claims priority to a provisional application filed on November 2, 2000 ("the Sullivan Provisional"), the Sullivan Provisional only includes sixteen figures. Section **[0055]** of Sullivan and FIG. 23 are not included in the Sullivan Provisional, and there appear to be no other portions of the Sullivan Provisional that would correspond to or otherwise provide support for section [**0055**] or FIG. 23. Accordingly, the cited passage of Sullivan is not entitled to the December 4, 2000 priority date.

In the Final Office Action, the Examiner stated that section **[0055]** and FIG. 23 are supported on page 19, lines 13-20, of the Sullivan Provisional. This section of Sullivan is reproduced below:

> The health care professional has access to a medical risk database 14 maintained on a data storage medium. The database 14 associates certain medical data in the patient data record 22 with additional medical care. The health care professional uses a data processor 16 to compare the medical data presented by the patient data record 22 with the medical data in the medical risk database 14 to identify whether medical data presented by the patient is associated with a risk of missed medical care opportunity. If so, information about additional medical care that would reduce the risk of a missed medical care opportunity is presented to the attending medical health care professional.

This cited material from the Sullivan Provisional is not the same as or similar to the material of Sullivan relied upon by the Examiner. Nothing in this section includes any discussion of content similar to that of FIG. 23 of Sullivan. Moreover, like FIG. 23 of Sullivan, this material from the Sullivan Provisional fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claims 12 and 13 or "*selecting for a given health care facility* a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection" as required by claims 22 and 37. On the contrary, the passage above describes a medical risk database that stores medical risks associated with a patient, but fails to suggest anything related to surgical procedures. In addition, the passage above fails to describe anything that is selectable for a given health care facility, in any way. The rejection of any claims based on the cited teaching of Sullivan is clearly erroneous, and should be overturned.

In the final Office Action, the Examiner also recognized that the combination of Mangram, Ormond-Walshe, Blume, Mushabac and Sullivan fails to suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices" as required by all pending independent claims. For this feature, the Examiner cited column 6, lines 9-20, of Afsah. However, Afsah was filed after Appellant's current case, and this relied upon passage of Afsah is not supported by the Afsah Provisional date.

In the Office Action, the Examiner indicated that FIG. 16 of the Afsah Provisional supports the passage at column 6, lines 9-20, of Afsah. However, FIG. 16 of the Afsah Provisional is merely a graph that isn't even described in the Afsah Provisional. One or ordinary skill in the art would find no support for the subject matter of column 6, lines 9-20, in FIG. 16 of Afsah. Accordingly, the relied upon passage at column 6, lines 9-20, of Afsah is not entitled to the Afsah Provisional date, and the cited passage of Afsah at column 6, lines 9-20 is not prior art to Appellant's claims.

Furthermore, regardless of whether Afsah is entitled to the priority date of the Afsah Provisional, Appellant also notes that the cited passage of Afsah does not disclose or suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." The passage of Afsah at column 6, lines 9-20, is reproduced below:

> Although the above method for determining the benchmark value of a particular indicator is preferred, there are other ways of identifying a benchmark value. For example, either the limit value of an indicator mandated by compliance regulations, or an historical baseline value can be used as the benchmark value for an indicator. Also the quartile approach can he used where the data group of indicator values is divided into quartiles and the worst value from the best quartile is selected as the benchmark value. Similarly, the best 10% approach can be used where the best 10% of the indicator value data group is selected and the worst value of the best 10% is designated as the benchmark value.

In this case, the so-called "benchmark value" is a benchmark for air admissions, used to help measure environmental performance. Indeed, Afsah is not even relevant to health care, much less the features of Appellant's claims. The passage above does not suggest any compliance indicator that indicates compliance with the one or more health care practices, as required by

Appellant's claims, much less a compliance indicator that quantifies a measure of quality associated with delivery of corresponding health care delivery practices. Accordingly, for yet these additional reasons, i.e., that the cited portion of Afsah is not prior art to Appellant's invention and not even relevant to health care, much less the features of Appellant's claims, the current rejections of all pending claims are improper and should be reversed.

Appellant is perplexed by the Examiner's comments in the Examiner's Answer insofar as the Examiner appeared to be re-stating some or all of the same arguments without actually addressing any of Appellant's detailed observations and replies to such arguments. For example, the Examiner provided four headings of "response to arguments," which Appellant had specifically addressed in detail in the previous Appeal Brief. These "response to arguments" in the Examiner's Answer are not any response to Appellant's detailed analysis of such arguments in the Appeal Brief, but appear to be a verbatim copy of previous comments by the Examiner in the Final Office Action, which are actually responsive to previous comments and not responsive to the Appeal Brief.

In other words, notwithstanding the fact that Appellant has responded to the Examiner's "response to arguments," with detailed analysis in the Appeal Brief, the Examiner appeared to be stating the same assertions in the Examiner's Answer without addressing any of the specific discussion of Appellant's Appeal Brief.

For example in the paragraph labeled "(1)" in the Response to Arguments section of the Examiner's Answer, the Examiner stated that Appellant is arguing that Mushabac and Blume references cannot be combined since they are non-analogous. Although Appellant agrees that Mushabac and Blume are non-analogous, Appellant's current arguments articulate missing features of Appellant's claims relative to Mushabac or Blume or any purported combination of these references. Appellant's argument is not merely that Mushabac and Blume are non-analogous.

In particular, as explained previously and outlined again in detail above, nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or techniques that generate a flag when a given health care delivery practice associated with the surgical procedure

is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Blume and/or Mushabac with the teaching of Mangram or Ormond-Walshe.

As another example, in the paragraph labeled "(2)" in the Response to Arguments section of the Examiner's Answer, the Examiner cited to sections of the Sullivan Provisional that Appellant's addressed in great detail in the Appeal Brief as failing to support the Examiner's assertions. Indeed, Appellant explained, in detail in the Appeal Brief, that some of the cited material from the Sullivan Patent is not even included in the Sullivan provisional application (namely FIG. 23). In addition, Appellant also explained that the other cited portions of the Sullivan Provisional are not the same as or similar to the material of Sullivan relied upon by the Examiner in the rejections. Moreover, Appellant also explained that like FIG. 23 of Sullivan, the relied upon material from the Sullivan Provisional fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claims 12 and 13 or "selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection" as required by claims 22 and 37.

As yet another example, in the paragraph labeled "(3)" in the Response to Arguments section of the Examiner's Answer, the Examiner indicated that FIG. 16 of the Afsah Provisional supports the passage at column 6, lines 9-20, of Afsah. However, Appellant explained in detail in the prior Appeal Brief that FIG. 16 of the Afsah Provisional is merely a graph that is not even described in the Afsah Provisional. Moreover, one or ordinary skill in the art would find no support for the subject matter of column 6, lines 9-20, in FIG. 16 of Afsah. Accordingly, the relied upon passage at column 6, lines 9-20, of Afsah is not entitled to the Afsah Provisional date, and the cited passage of Afsah at column 6, lines 9-20 is not prior art to Appellant's claims.

Furthermore, regardless of whether Afsah is entitled to the priority date of the Afsah Provisional, Appellant also noted in the prior Appeal Brief that the cited passage of Afsah does not disclose or suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." The Examiner also did not appear to address this issue in the Examiner's Answer. As detailed above and

argued previously by Applicant, the cited passage of Afsah not even relevant to health care, much less the features of Appellant's claims. The cited passage of Afsah does not suggest any compliance indicator that indicates compliance with the one or more health care practices, as required by Appellant's claims, much less a compliance indicator that quantifies a measure of quality associated with delivery of corresponding health care delivery practices.

As a final point, Applicant also disputes the contentions in the paragraph labeled "(4)" in the Response to Arguments section of the Examiner's Answer, and submits that the Examiner advancing contradictory positions with respect to claim 22. In this section, the Examiner contends that Jacober (specifically claims 32-34 of Jacober) suggests "identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure." However, this feature appears in claim 22, which was not rejected based on the Jacober reference. Jacober was not even cited in the rejection of claim 22, and therefore the comments under paragraph labeled "(4)" in the Response to Arguments section of the Examiner's Answer (which cite features of claim 22 as being disclosed in Jacober) are not even consistent with the rejections on Appeal.

Jacober was cited in the rejections of dependent claims 23-25 (not claim 22), yet the comments under paragraph labeled "(4)" in the Response to Arguments section of the Examiner's Answer recite features of claim 22 as being disclosed in Jacober. In any case, notwithstanding these inconsistencies in the rejections advanced by the Examiner relative to the comments in paragraph labeled "(4)" in the Response to Arguments section of the Examiner's Answer, the record should clearly reflect that Jacober lacks relevance to claim 22, as well as dependent claims 23-25. Indeed, the cited passages of Jacober (i.e., claims 32-34 of Jacober) recite methods for dispensing medication and monitoring the dispensing of medication, which lack any relevance to the features of claim 22 or the features of dependent claims 23-25.

Dependent claims 34-36 (being argued under separate heading)

Appellant requests a separate review of dependent claims 34-36. In addition to the errors outlined above, Appellant respectfully notes that dependent claims 34-36 have not yet been addressed in any Office Action or the Examiner's Answer. In the Final Office Action and the previous Office Action, the Examiner failed to address claims 34-36, but merely stated that "as per claims 26-37,[65] these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." This statement by the Examiner is incorrect. Claims 34-36 present features that the Examiner has not considered or addressed in any Office Action. Claims 34-36 read as follows:

> Claim 34: The method of claim 22, further wherein the compliance indicator defines a value within a pre-established quality scale.
>
> Claim 35: The method of claim 34, wherein the quality scale ranges from 1 to 10.
>
> Claim 36: The method of claim 22, further comprising generating a report that represents a compilation of measurement data associated with the surgical procedure.

None of these features of claims 34-36 have even been addressed in any Office Action to date, and for this reason, the rejections must be reversed.

As with other arguments, the Examiner's Answer did not appear to even address dependent claims 34-36, which were also argued under a separate heading in the previous Appeal Brief. Like the Final Office Action, the Examiner's Answer merely asserted that: "as per claims 26-35 and 37,[66] these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." This statement by the Examiner is incorrect, and the Examiner again failed to even address Appellant's arguments. The rejections of claims 34-36 must be reversed.

---

[65] In the Final Office Action, the Examiner changed this portion to state "as per claims 26-35 and 37 these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." The Examiner mentioned claim 36 with claim 22, but again failed to address any of the features of claim 36 in any substantive discussion.

[66] Relative to a previous Office Action that also mentioned claim 36 in this section, in the Final Office Action (and again in the Examiner's Answer), the Examiner had changed this portion of the discussion to state "as per claims 26-35 and 37 these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." The Examiner mentioned claim 36 with claim 22, but again failed to address any of the features of claim 36 in any substantive discussion.

THIRD GROUND OF REJECTION UNDER APPEAL

The third ground of rejection to be reviewed on appeal is the rejection of claims 23-25 under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe, in further view of Blume, in further view of Mushabac, in further view of Sullivan, in further view of Afsah, and in further view of Jacober.

Appellant requests a separate review of dependent claims 23-25. In the June 20, 2006 Office Action, the Examiner had rejected a former set of claims 12-32 under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe, and further in view of Jacober (US 6,662,081). However, these rejections were subsequently overcome, and therefore, the Examiner's mention of Jacober, and the rejections of claims 23-25 based on Mangram in view of Ormond-Walshe, and further in view of Jacober appears to be improper.

In the rejections of dependent claims 23-25, the Examiner's Answer referred to Jacober and clarified that these claims were being rejected based on a seven-way combination of Mangram in view of Ormond-Walshe and in further view of Blume and in further view of Mushabac and in further view of Sullivan and in further view of Afsah and in further view of Jacober.

Claims 23-25 are dependent upon claim 22. Claim 23 clarifies that identifying when the data indicative of the given practice is not in compliance with the rule comprises generating a flag for the data. Claim 24 further requires prompting medical personnel to take further action when the flag is generated. Claim 25 further requires clearing the flag when the further action is taken.

Nothing in Jacober or any of the applied references discloses or suggests identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure, which is required by claim 22 from which claims 23-25 depend. Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Jacober with the teaching of Mangram or Ormond-Walshe as theses teaching are totally unrelated and concern totally different areas of endeavor.

The Jacober reference describes a medication regimen container and system. In particular, Jacober describes a medication dispensing unit that can be programmed to signal proper medication dosages to a user, and the times of such dosages. Nothing in Jacober

discloses or suggests the identification of when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). Indeed, Jacober does not even relate to surgical procedures, whatsoever.

Appellant disputes the Examiner's conclusions that a person of ordinary skill in the art would have been motivated to (or found any rational reason) to have modified the teachings of Mangram and Ormond-Walshe in further view of Jacober (as part of a seven-way combination of prior art references) to arrive at a computerized system for managing surgical site infection incident to the surgical procedure by generating flags when a given health care practice associated with the surgical procedure is not in compliance with a rule.

Indeed, the teaching of Jacober is completely unrelated to that of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Jacober. To be sure, Jacober concerns a medical regimen container for managing the dispense of medication, and has no relevance in the field of surgical procedures whatsoever, much less management of risks of surgical site infection incident to the surgical procedure. Thus, even if Jacober could be reasonably construed as generating a flag, the flag of Jacober relates to the dispensation of medication from a programmable container, and has no relevance to a surgical procedure nor the management of risks of surgical site infection incident to the surgical procedure.

CONCLUSION OF ARGUMENT

The Examiner has failed to meet the burden of establishing a prima facie case of obviousness with respect to Appellant's claims.

Appellant respectfully requests separate review by the Board for set of claims addressed above under separate headings. Appellant notes that several different arguments have been presented with respect to the independent claims, and Appellant specifically requests that the board consider each of these arguments individually, and all of these arguments collectively.

Respectfully submitted,

/Nancy M. Lambert/

Nancy M. Lambert
Registration No. 44,856
Attorney for Applicants

NML:jlh\#957096 Response to Examiners Answer 6-10-10
Office of Intellectual Property Counsel
3M Innovative Properties Company
P.O. Box 33427
St. Paul, Minnesota 55133-3427
(651) 733-2180
Facsimile: (651) 736-3833

Dated: August 10, 2010

CLAIMS APPENDIX

Claims 1-11 (Canceled).

Claim 12 (Previously presented): A computer-implemented system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the computer-implemented system comprising:

means for identifying a plurality of stages of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage and a postoperative stage;

means for identifying one or more points-of-care within each identified stage of operative care associated with the surgical procedure;

for each point-of-care associated with the surgical procedure, means for identifying one or a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility;

means for identifying one or more compliance indicators associated with the surgical procedure for the one or plurality of health care delivery practices associated with the surgical procedure within each point-of-care associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators, wherein at least some of the

compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices; and

for each of the compliance indicators, means for generating a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby align the health care delivery practices associated with the surgical procedure into rule compliance and to provide a perioperative process map of delivery practices spanning the plurality of stages of operative care associated with the surgical procedure to thereby manage the risk or occurrence of surgical site infection incident to the surgical procedure.

Claim 13 (Previously presented): A system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the system comprising:

(a) means for constructing a perioperative process map of practices for the delivery of the surgical procedure, the map comprising a plurality of health care delivery practices associated with the surgical procedure and one or more indicators of compliance with the one or more health care practices, wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility, and wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care practices; and

(b) means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure, wherein the means for monitoring the compliance indicators generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure.

Claim 14 (Original): The system of claim 13 further comprising means for recording the compliance indicators.

Claim 15 (Original): The system of claim 13 wherein the monitoring means comprises a software-encoded information management device.

Claim 16 (Original): The system of claim 13 wherein the monitoring means comprises a software-encoded information management device that is capable of operating across a network of computers.

Claim 17 (Original): The system of claim 15 wherein the information management device is delivered to one or more users via the internet.

Claim 18 (Original): The system of claim 13 further comprising means for monitoring one or more indicators of outcome.

Claim 19 (Previously presented): The system of claim18 wherein the outcome is the rate of the incidence of surgical site infection.

Claim 20 (Previously presented): The system of claim18 wherein the outcome is the patient satisfaction.

Claim 21 (Previously presented): The system of claim18 wherein the outcome is cost.

Claim 22 (Previously presented): A computer-implemented method for managing risks of surgical site infection incident to a surgical procedure, the method comprising:

selecting, via a computer, for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection;

evaluating, via the computer, a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure;

storing, via the computer, data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure; and

identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure, wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.

Claim 23 (Previously presented): The method of claim 22, wherein identifying when the data indicative of the given practice is not in compliance with the rule comprises generating a flag for the data.

Claim 24 (Previously presented): The method of claim 23, further comprising prompting medical personnel to take further action when the flag is generated.

Claim 25 (Previously presented): The method of claim 24, further comprising clearing the flag when the further action is taken.

Claim 26 (Previously presented): The method of claim 22, further comprising generating a perioperative process map of a plurality of practices in a plurality of stages, the plurality of stages including at least a prepoperative stage, an intraoperative stage, and a postoperative stage.

Claim 27 (Previously presented): The method of claim 26, further comprising for each stage of the perioperative process map:

evaluating practices that pose infection risks during the given stage of the surgical procedure;

storing data indicative of each of the practices as executed by one or more persons involved with the surgical procedure; and

identifying when the data indicative of any of the practices is not in compliance with a rule established for the given practice.

Claim 28 (Previously presented): The method of claim 27, wherein identifying when the data indicative of any of the practices is not in compliance with the rule established for the given practice comprises generating a flag for the data indicative of one of the practices not in compliance with the rule established for that practice.

Claim 29 (Previously presented): The method of claim 28, further comprising prompting medical personnel to take further action when the flag is generated.

Claim 30 (Previously presented): The method of claim 29, further comprising clearing the flag when the further action is taken.

Claim 31 (Canceled).

Claim 32 (Previously presented): The method of claim 22, wherein the computer-implemented method is implemented by the computer in hardware.

Claim 33 (Previously presented): The method of claim 22, further comprising:

evaluating each of a plurality of practices associated with the surgical procedure that pose infection risks during the surgical procedure;

storing data indicative of each of the practices as executed by one or more persons involved with the surgical procedure; and

identifying when the data indicative of one or more of the practices associated with the surgical procedure is not in compliance with a respective rule established for a respective practice.

Claim 34 (Previously presented): The method of claim 22, further wherein the compliance indicator defines a value within a pre-established quality scale.

Claim 35 (Previously presented): The method of claim 34, wherein the quality scale ranges from 1 to 10.

Claim 36 (Previously presented): The method of claim 22, further comprising generating a report that represents a compilation of measurement data associated with the surgical procedure.

Claim 37 (Previously presented): A computer-implemented system for managing risks of surgical site infection incident to a surgical procedure, the system comprising:

means for selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection;

means for evaluating a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure;

means for storing data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure; and

means for identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure, wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.

Claim 38 (Previously presented) The system of claim 37, wherein means for identifying via the compliance indicator when the data indicative of the given practice is not in compliance with the rule comprises means for generating a flag for the data.

Claim 39 (Previously presented): The system of claim 38, further comprising means for prompting medical personnel to take further action when the flag is generated.

Claim 40 (Previously presented): The system of claim 39, further comprising means for clearing the flag when the further action is taken.

Claim 41 (Previously presented): The system of claim 37, further comprising means for generating a perioperative process map of a plurality of practices in a plurality of stages, the plurality of stages including at least a prepoperative stage, an intraoperative stage, and a postoperative stage.

Claim 42 (Previously presented): The system of claim 41, further comprising for each stage of the perioperative process map:

means for evaluating practices that pose infection risks during the given stage of the surgical procedure;

means for storing data indicative of each of the practices as executed by one or more persons involved with the surgical procedure; and

means for identifying when the data indicative of any of the practices is not in compliance with a rule established for the given practice.

Claim 43 (Previously presented): The system of claim 42, wherein means for identifying when the data indicative of any of the practices is not in compliance with the rule established for the given practice comprises means for generating a flag for the data indicative of one of the practices not in compliance with the rule established for that practice.

Claim 44 (Previously presented): The system of claim 43, further comprising means for prompting medical personnel to take further action when the flag is generated.

Claim 45 (Previously presented): The system of claim 44, further comprising means for clearing the flag when the further action is taken.

Claim 46 (Previously presented): The system of claim 37, further comprising:

means for evaluating each of a plurality of practices associated with the surgical procedure that pose infection risks during the surgical procedure;

means for storing data indicative of each of the practices as executed by one or more persons involved with the surgical procedure; and

means for identifying when the data indicative of one or more of the practices associated with the surgical procedure is not in compliance with a respective rule established for a respective practice.

Claim 47 (Previously presented): The system of claim 37, further wherein the compliance indicator defines a value within a pre-established quality scale.

Claim 48 (Previously presented): The system of claim 47, wherein the quality scale ranges from 1 to 10.

Claim 49 (Previously presented): The system of claim 37, further comprising means for generating a report that represents a compilation of measurement data associated with the surgical procedure.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE